

Additionally, in reply to the Final Office Action mailed March 27, 2002, Applicants respectfully request reconsideration of the rejections and objections in the Office Action mailed March 27, 2002, (hereinafter "Office Action"), prior to the issuance of an action in response to the filing of the attached Continued Prosecution Application.

In the instant Continued Prosecution Application, claims 16-26, 37 and 38 will be pending. The Office Action lists claims 16-26 as rejected and claims 37 and 38 as objected to.

Attached hereto as Appendix A is a marked-up version of the changes made to the claims by the current amendments. Appendix A is captioned "Version with markings to show changes made".

The Examiner has maintained the rejection under 35 U.S.C. §112, first and second paragraphs. Applicants respectfully traverse the rejection. The Examiner alleges that Applicants have not shown that the full scope of the compounds can be made or would be active as receptor tyrosine kinase antagonists.

Applicants point out that it is a well-accepted principle of chemical patents that "[i]t is not a function of the claims to specifically exclude...possible inoperative substances...", In re Dinh-Nguyen, 181 USPQ 46, 48 (CCPA 1974). This quote reflects two steadfast holdings of patent law, first, no working examples must be provided to support a claim and second, it is impracticable to make most, much less all, of the species of a chemical genus to support a claim. The foregoing is reflected in the following detailed discussion.

Applicants have enabled how to make the compounds that are within the scope of Claim 16. Applicants direct the Examiner's attention to Applicants arguments in the Amendments and Response mailed November 26, 2001. More particularly, Applicants point out that generally it is not necessary to actually make any compounds so long as one names and discloses how to make a sufficient number of representative compounds to support a broad scope and how to use such compounds. Even though compounds are not actually required to be made, Applicants point out that many compounds have been synthesized in support of the instant application. Applicants respectfully contend that the "Detailed Description" and "Examples" (especially Examples 295-297) section as pointed out in the Response mailed November 26, 2001, enable how to make the compounds of Claim 16. It is not necessary and not required by the applicable authorities for the Applicants to provide an example of compounds for each value of the variables:

It is manifestly impracticable for an applicant who discloses a generic invention to give an example of every such species. It is sufficient if the disclosure teaches those skilled in the art what the invention is and how to practice it. In re Kamal, 398 F. 2d 867, 158 USPQ 321, 323 (CCPA 1968), quoting In re Grimme, 274 F. 2d 949, 124 USPQ 499, 501 (CCPA 1960).

With respect to the Examiner's citation of In re Lund, 153 USPQ 625, alleging that it stands for the proposition that "[t]he instant case is similar to In re Lund 153 USPQ 625, in which the Court agreed the specific aldehyde reactants mentioned in the specification fell within a limited range and thus far short of the claims' scope", Applicants point out that In re Lund is not on-point with the instant rejection. The issue in In re Lund revolved around the fact that the application at issue did not define the terms "aralkyl" and "mononuclear aralkyl". In re Lund, 54 CCPA 1365. Since the terms were not defined in the specification the court gave it the broadest definition according to the art and found the application lacking in supporting the broadest reaches of the definitions. This is not the situation in the instant case. The definitions of "aliphatic groups" and "aromatic groups" are given, *inter alia*, at page 11 of the instant specification and the substituents that can be substituted onto the moieties described as being substituted are given at pages 11 and 12 of the instant specification. Further, Applicants provide many more examples of compounds that bear different embodiments of aliphatic groups and aromatic groups than in In re Lund.

Notwithstanding the foregoing, Applicants direct the Examiner to the Court of Customs and Patent Appeals (CCPA), which has now been superseded by the Court of Appeals for the Federal Circuit, stated in In re Borkowski, 164 U.S.P.Q. 642 (C.C.P.A. 1970) that: "[T]here is no magical relation between the number of representative examples and the breadth of the claims; the number and variety of examples are irrelevant if the disclosure is 'enabling' and sets forth the 'best mode contemplated.'" *Id.* at 646. Applicants have submitted such an enabling disclosure as detailed in the Response mailed November 26, 2001. Applicants have, therefore, complied with the statutory requirements of §112.

Further, the Examiner must provide reasoned and detailed arguments as to why the Examiner does not believe that the compounds falling within the scope of Applicants' claim but not exemplified cannot be made using the knowledge of one of ordinary skill in the art as enabled by Applicants' disclosure. Without a reasoned and detailed argument by the Examiner as to the

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compounds claimed in Claim 16 (not any broad brush stroke comment regarding organic compounds in general), Applicants statements regarding enablement must be accepted by the Office. In support of this argument, Applicants direct the Examiner's attention to In re Marzocchi et al., which states:

As a matter of PTO practice, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt does exist, a rejection for failure to teach how to make and/or use will be proper on that basis; such a rejection can be overcome by suitable proofs indicating that the teaching contained in the specification is truly enabling. (emphasis in original). In re Marzocchi et al., 169 USPQ 367 at 370 (CCPA 1971).

To date, the Examiner has just asserted that he doubts that the full scope of the genus could be made. The Examiner has not given a reasoned statement as to why any major portion of the compounds claimed in the instant application could not be made or would not be active as antagonists of receptor tyrosine kinases. Therefore, the specification disclosure must be taken as in compliance with the requirements of the first paragraph of section 112 unless there is reason to doubt the objective truth of the statements contained therein.

The Examiner states at page 3 of the Office Action that "no reasons and evidence have been provided to support applicants' position". As mentioned hereinabove, the burden is not on the Applicants in the first instance, it is upon the Examiner. In order to shift the burden to Applicants, the Examiner must present factual evidence to doubt the truth of Applicants' statements regarding enablement. To date, the Examiner has only cited cases that speak in generalities that are not specifically applicable to Applicants' instant claims. The Examiner will note that the cases cited by the Examiner refer to specific compounds, claims and disclosures that were at issue and not to Applicants' compounds, claims and disclosure. Accordingly, the burden is still with the Office to refute Applicants' assertions.

Based upon the foregoing, Applicants believe that the rejection of claims 16-26 and 36 under 35 U.S.C. §112, first paragraph, should be withdrawn.

The Examiner has rejected claims 16-26 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification. The Examiner states that the provisos Applicants have added in claim 16 are not literally to be found in the specification and cites Ex parte Grasselli. Applicants respectfully traverse the rejection. Applicants disagree with the Examiner's interpretation of the holding in Ex parte Grasselli. Ex parte Grasselli involved the way Grasselli attempted to avoid the prior art, namely by adding a negative limitation that in effect broadened the scope of the original claim. In point of fact, the Board stated "[i]t might be added that the express exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded". Ex parte Grasselli, 231 USPQ 393, 394 (Bd. App. 1983). The holding of the Board had more to do with the way the negative limitation was worded so that the claim at issue actually claimed more than it originally did. This is not the same as the situation in the instant application. The provisos in Applicants' claim specifically carve out compounds that were in the prior art. The provisos result in a narrower scope of the original claim and does not result in the inclusion of elements because they are not specifically excluded. Therefore, the provisos does not give rise to the same issue that the Board in Ex parte Grasselli held against.

Further, in support of the provisos, Applicants direct the Examiner's attention to *In re Edward*, 568 F.2d 1349, 1351-1352 (CCPA 1978), which supports Applicants' position that *ipsis verbis* disclosure is not necessary to satisfy the written description requirement of 35 USC 112 ¶1. See *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996); *In re Edwards*, 568 F.2d 1349, 1351-52 (CCPA 1978) (asserting that all that is required is that the Application reasonably convey to persons skilled in the art that, as of the filing date, the inventor had possession of the subject matter later claimed by him). Furthermore, inquiry into the question of whether a particular claim complies with the written description requirement of 35 USC 112 ¶1 is a factual one that must be assessed on a case-by-case basis. See *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed. Cir. 1991) (reviewing with approval a line of CCPA cases that stressed the fact specificity of inquiries regarding compliance with the written description requirement of 35 USC 112 ¶1).

Applicants respectfully contend that the proviso in the previous Response does not undermine the claim's patentability vis-a-vis the written description requirement of 35 USC

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11291 because the mere lack of literal support for the proviso in the application as filed is insufficient to support the Examiner's rejection. See *In re Edwards*, 568 F.2d 1349, 1354 (CCPA 1978) (holding that the USPTO must also supply reasoning as to why a claim lacking literal support fails to comply with the written description requirement of 35 USC 11291).

Furthermore, the Applicants respectfully contend that the application, at the time it was filed, would have reasonably conveyed to one of ordinary skill in the arts of organic and medicinal chemistry that the Applicants were in possession of the subject matter of claim 16 as amended because the amended claim reads on the bulk of the exemplification provided in the application. See *In re Johnson*, 558 F.2d 1008, 1019 (CCPA) (stating "[t]he notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species there thin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of [35 USC] 112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute"). Additionally, the Applicants respectfully assert that because the application, at the time it was filed, supported claim 16 as originally filed, i.e., prior to its amendment to include the proviso, the application, at the time it was filed, necessarily supports claim 16 as amended. See *In re Johnson*, 558 F.2d 1008, 1019 (CCPA) (holding that "the specification, having described the whole, necessarily described the part remaining").

Based upon the foregoing, the rejection of claims 16-26 under 35 U.S.C. §112, first paragraph, should be withdrawn.

The Examiner has rejected claims 16-26 under 35 U.S.C. §112, second paragraph, for the reasons detailed at page 5 of the Office Action. Applicants maintain the traversal of the rejection. Applicants also refer the Examiner to Applicants' arguments in the prior response on this rejection. Additionally, Applicants point out that the reference to the definition of "heteroaryl" in the specification was not intended as an indication that the definition of the term should be read into the claim, rather it was to point out that the specification provides a definition and examples of heteroaryl that one of ordinary skill in the art would understand. Thus, in light of the definition in the specification, the term in the claim is not indefinite. That is, it has metes and bounds. For example, the term does not include aryl groups without heteroatoms and it does not include groups that have heteroatoms but are not aromatic. Further, there is no per se rule against the use

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of an open ended term as the Examiner implies at page 5 of the Office Action. In fact, the term "comprising" is an open ended term that is a standard term used in patents.

Applicants respectfully point out that this issue is inappropriately placed under the 35 U.S.C. §112, second paragraph, rejection since the arguments presented by the Examiner seem to be a doubt as to enablement, which is already addressed hereinabove.

The same arguments are applicable to the term "substituent". The specification clearly defines the term as referring to a chemical moiety that can be attached to that portion of the molecule that the term modifies. The specification also states that one of ordinary skill in the art would know what such substituents can be and provides examples as a further guide to the definition.

Applicants have amended claims 20 and 21 so that it no longer includes "tetrahydrofuran".

Accordingly, Applicants believe that the rejection of claims 16-26 under 35 U.S.C. §112, second paragraph, is obviated and should be withdrawn.

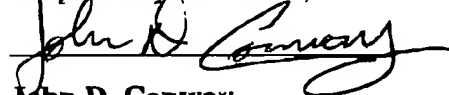
Based upon the foregoing, Applicants believe that claims 16-26, 37 and 38 are in condition for allowance. Prompt and favorable action is earnestly solicited.

If the Examiner believes that a telephone conference would advance the condition of the instant application for allowance, Applicants invite the Examiner to call Applicants' attorney at the number noted below.

Date:

Sept. 27, 2002

Respectfully submitted,



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